DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 20, 2004

Mr. Chris Lin, President
Seven Seas Seafoods, Inc.
901 S. Fremont Ave., Suite 168
Alhambra, CA 91803

W/L 20-04

Dear Mr. Lin:

On December 16, 2003, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 901 S. Fremont Ave., Suite 168, Alhambra, CA 91803. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulations, Title 21 of the Code of Federal Regulations Part 123 (21 CFR § 123).

The Seafood HACCP Regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as HACCP in accordance with U.S. requirements. Failure of a processor, foreign or domestic, to have and implement a HACCP plan that complies with the requirements 21 CFR § 123, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 342(a)(4)). You may find the Act and the seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

During our inspection, the FDA investigator observed serious deviations in your seafood HACCP program, including failure to comply with the importer verification requirements listed in the Seafood HACCP Regulations, Section 123.12, "Special Requirements for Imported Products". The FDA investigator also provided you with a copy of the FDA 483, Inspectional Observations, which presents an evaluation of your firm's performance regarding various aspects of the HACCP requirements. Accordingly, the frozen yellowfin tuna imported by your firm and inspected on the above date is adulterated in that the product has been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

The HACCP deviations were as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm could not provide product specifications for frozen yellowfin tuna loin imported from [redacted]t the time of the inspection for a recent entry of this product.

This inspection was also a follow-up to a previous inspection conducted April 2, 2003 to verify that corrective actions to seafood HACCP importer verification deviations had taken place for frozen belt fish. A copy of the FDA 483 was also given to you as a result of that inspection. At the most recent inspection, you informed the investigator that you no longer import frozen belt fish from the[redacted]. Nonetheless, this previous inspection should have served as prior notice that your importing practices for fish and fishery products are subject to 21 CFR § 123.

The above identified deviation is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed, imported and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct this Seafood HACCP deviation. Failure to promptly do so may result in regulatory action without further notice. Such action may include seizure and/or injunction. FDA may also detain your seafood products without examination.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter of specific steps you have taken to correct this violation, including an explanation of each step taken to prevent its recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to:

U.S. Food & Drug Administration
Attn: John L. Stevens
Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

If you have questions regarding the implementation of the Seafood HACCP Regulations, you may contact Ruth P. Dixon, Compliance Officer, at (310) 971-2299.

Sincerely,

Alonza E. Cruse
District Director